

## Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma

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*Received: 26 June 2015; accepted: 12 August 2015*

Patent is a significant subject matter since it provides monopoly to the inventor over his invention and restrict others to use the invention as it gives exclusive right to the patentee. The monopoly can cause rise in the cost of goods and services as the patentee holds the complete right to decide the price of his invention. This can pose a problem to the developing countries as they do not have many resources or funds to buy such costly patented products especially drugs and medicines. TRIPS Agreement in 1995 provided the provision of compulsory license under Section 31, which supports granting of right to manufacture the patented product by the government or a third party authorized by the government without the consent of the inventor. Later, Doha Declaration also supported TRIPS not only in granting compulsory license but also to import the patented drug by the countries which are in great need of that drug but are unable to manufacture it. This article discusses about the need of compulsory license and how various countries are exploring this provision and various issues related to compulsory license of drugs and pharmaceuticals along with the positive contribution of compulsory licensing in providing the access of the life-saving drugs whenever required by the public.

**Keywords:** Compulsory license, drugs and pharmaceuticals, TRIPS Agreement, Doha Declaration, Indian Patents Act

The government grants patent for the invention, which is novel, involves an inventive step and has commercial use. A patent grants exclusive rights to an inventor for a limited period of time, usually for 20 years, in exchange of detailed public disclosure of an invention. Patent provides exclusive right to the inventor to prevent others to make, use and sell the invention.<sup>1</sup> In the absence of competing products in the market, the patent holder enjoys market domination and therefore setting the price of the drug as per his own choice, causing 'monopoly' which may increase the possibilities of abuse of patent rights. The high prices of patented drugs may lead to their unaffordability and may restrict access of poor patients to medicines. Pricing of patented drugs is done on the basis of the degree of innovation of the new product. The drug products, which are therapeutic breakthrough, are priced high. Further other parameters, which also determine the pricing of the drug, include the cost of drug development, manufacturing cost, market share of drug, if it is used for some common disease or rare disease, clinical effectiveness, competitors or alternatives, etc. All these factors may lead to pricing of the patented drug to the maximum value so as to earn heavy profits causing 'monopoly' due to absence of perfect

competition in market. Some patented drugs have different pricing in different countries because of difference in market conditions and economy of a country. For example, price of 12.5 mg capsule of *Sunitinib Malate* (used for treatment of renal cancer and GI tract cancer) is INR 11731 in India, INR 92035 in France, INR 82539 in Australia and INR 104192 in New Zealand.<sup>2</sup>

Patent holder may abuse his patent rights by not commercializing the invention so as not to compete with his earlier commercialized invention since the commercialization requires the establishment of new manufacturing unit, new R&D and a lot of money. The patentee may commercialize or manufacture their product in richer countries to earn more revenue and prefer only to import in low developing countries. This may deprive the population of low developing countries from the benefits of patented product due to lack of money and other resources to have access. It is well known that the commercial working of patent is one of the important criteria of patent rights in various countries. For example, in India according to Section 146(2) and Rule 131(1), patentee has to mandatorily fill the Form 27 to provide information of the commercial working of his patent within 3 months at the end of each calendar year. Providing wrong information in Form 27 or not filling the form at all is a punishable offence.<sup>3</sup>

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### TRIPS Agreement and Compulsory Licensing of Drug Patents

In order to counter such abuses of patent rights, TRIPS (Agreement on Trade Related Aspects of Intellectual Property Rights) gave the provision of compulsory license so as to keep a check on the use of the invention on grounds of public morality.<sup>4</sup> TRIPS doesn't use the term 'compulsory license' as such. However according to Article 31 of the TRIPS Agreement, a patent can be used by the government or third parties authorized by the government, without the authorization of the right holder. Such authorization is given under certain conditions like, applicant has already made efforts to obtain license from the patentee (however this is not applicable in case of national emergency or extreme urgency conditions), non-commercial use, non-exclusive use, etc. Provision of providing the adequate remuneration to the patent holder by taking into account the economic value of the patent is also provided in

sub-paragraph (h) of Article 31 of TRIPS Agreement. Sub-paragraph (f) of Article 31 is most important, as it limits the benefits of compulsory license to the countries which have manufacturing capability as it says that the product is meant for domestic market only.<sup>5</sup> However, the countries which mostly have health crisis are developing countries or least developed countries which have low or no manufacturing capacities. No doubt, TRIPS provided a lot of benefits but there was need of amendment in TRIPS which was fulfilled by Doha Declaration in November 2001 in which it allowed the member country to issue compulsory license to produce drugs for export to the countries which establish that they have less or no manufacturing capacity of drugs.<sup>1</sup> Table-1 shows the examples of compulsory license of drug patents in various countries. Doha Declaration affirms to protect public health and to promote access to medicines for all without any discrimination. The implementation of decision occurred in August 2003.

Table1– Representative examples of compulsory license of drug patents in various countries

S. No.	Country	Year	Drug	Remarks
1	USA	2001	<i>Ciprofloxacin</i>	Reduction in 54% of original price of the drug <sup>37,38</sup>
2	Zimbabwe	2002	<i>Lamivudine and Zidovudine</i>	Reduction in price of drug helped Zimbabwe in the period of emergency for AIDS <sup>4,8</sup>
3	USA	2004	<i>Latanoprost and Ritonavir</i>	Due to threat under Bayh-Dole Act, Patent holder lowered the price of drug to affordable value <sup>8</sup>
4	Malaysia	2004	<i>Didanosine, Zidovudine and combination of Lamivudine and Zidovudine</i>	Two year compulsory license was issued to import the drugs from India <sup>8</sup>
5	Indonesia	2004	<i>Lamivudine and Nevirapine</i>	The generic version of drugs was available in very affordable price. The license was issued for government use, and it includes a royalty rate of 0.5% of the net selling value <sup>4</sup>
6	Mozambique	2004	<i>Lamivudine, Stavudine and Nevirapine</i>	The license was granted to local producer, Pharco Mozambique to produce fixed dose combination but the plan had to be shelved because the price of APIs was economically very high <sup>4,8</sup>
7	Zambia	2004	<i>Lamivudine, Stavudine and Nevirapine</i>	The license was granted to a local producer to produce a triple fixed dose combination <sup>4,8</sup>
8	Taiwan	2005	<i>Tamiflu</i>	In 2007, Taiwan drug firms can make Tamiflu for domestic use and should use it only when there is a shortage of supply from Roche <sup>4</sup>
9	Thailand	2007	<i>Lopinavir and Ritonavir</i>	These antiretroviral drugs came in approach of public due to reduction in their price. Royalty of 0.5% was given to the patent holder <sup>4,8</sup>
10	Thailand	2007	<i>Clopidogrel</i>	Myocardial ischemia and cerebro-vascular accident being the most serious public health burden because of high mortality and disability loss. Its mortality rate is in top three annual ranking. So with the grant of its compulsory license, the mortality rate got reduced <sup>4,8</sup>
11	Indonesia	2007	<i>Efavirenz</i>	Compulsory licensing reduced the price of drug and increased its accessibility <sup>4</sup>
12	Ecuador	2010	<i>Lopinavir and Ritonavir</i>	The patent was held by Abbott Pharmaceuticals. The term of license was the time that was left for the patent i.e. November 2014 <sup>39,40</sup>
13	Ecuador	2010	<i>Ritonavir</i>	Till 2014, Ecuador issued nine compulsory licenses for various drugs including <i>Sutinib, Certolizumab, Mycofenolate Sodium</i> etc <sup>41,42</sup>
14	Cameroon	2005	ARVs such as, <i>Lamivudine, Nevirapin, Zidovudine</i>	CL issued to essential inventions for manufacture of anti HIV drugs <sup>43</sup>
15	Eretria	2005	Anti HIV/AIDS drugs	Compulsory license issued to import Anti HIV drugs <sup>43</sup>
16	Guinea	2005	Anti HIV/AIDS drugs	Compulsory license issued to import Anti HIV drugs <sup>43</sup>

Rwanda was the first country to use this system. Rwanda managed to import antiretroviral drug *TriAvir* from a Canadian generic company Apotex.<sup>6</sup>

Later on, many companies have been voluntarily making proactive efforts to genuinely make their drugs accessible due to threat of compulsory license. Some have effectively lowered prices of their inventions while others have offered voluntary, royalty-free licenses to other companies. For example, in September 2014, *Gilead* signed non-exclusive licensing agreements with seven India-based generic pharmaceutical manufacturers to manufacture *Sofosbuvir* and the investigational single tablet regimen of *Ledipasvir/Sofosbuvir* for distribution in 91 developing countries.<sup>7</sup> Brazil, a middle-income country, has actively used compulsory license as a threat to negotiate lower prices for AIDS drugs like *Nelfinavir*, which was a patented product of Roche. The company reached an agreement to sell the drug in Brazil at an additional discount of 40%, in return Brazil will not issue compulsory license.<sup>8</sup>

Indian Government has issued its first compulsory license in 2012 for the drug *Nexavar*, an anti-cancer drug. Many other countries like, Malaysia, Indonesia, China, Taiwan, Mozambique, Zambia, Zimbabwe, etc. have granted compulsory license for various drugs.<sup>8</sup> Many countries still have not explored the power of compulsory licensing. It has been observed that the political strength of the licensing country plays very important role in granting the compulsory license of the invention. The grant of first compulsory license by Indian government became an eyesore for multinational drug companies and USA and so it issued Report 301. Under Section 301 of Trade Act of 1974, the United States Trade Representative (USTR) issues an Annual Report in which those countries which could not protect the intellectual property rights of US companies are identified and threatened.<sup>9</sup> In this report USA claimed that India needs to modify its IP rules and regulations specifically on compulsory license and Section 3(d). USTR placed India on the 'Priority Watch List' along with other countries.<sup>10</sup>

The benefit of compulsory license has mainly come into picture due to restricted access of medicines in developing and under-developed countries but lack of political strength in such countries is an obstacle in exploring compulsory license and does not hence make significant impact in improving access to patented inventions. Besides so many benefits of compulsory license, there are some issues related to it

such as, development of gray markets; lesser royalty, decreased creativity in inventors, etc. which also raises questions on compulsory licensing provisions. Clarifying these uncertainties will not only improve efficiency in utilizing compulsory licenses but may also encourage nations to issue compulsory licenses without concerns of political criticism.

### Compulsory License Provisions in The Indian Patents Act

India is one of the important member countries to sign the TRIPS Agreement, which got implementation in India in 2005. Before the TRIPS regime, product patents for drugs as well were not granted in India. That was the time when generic industry of drugs greatly flourished in India inspite of strict patent regime in developed countries. This system has its own benefits like there was no problem in accessibility of drugs available in India. Also the price of drugs was very nominal, even of the drugs which were very costly in other countries. Accessibility of drugs at very low price is one of the important requirements of the developing nations.<sup>1</sup> But there was a problem with this system that the new and innovative drugs could not be launched in India. To solve this problem, India signed TRIPS Agreement in 1995. Now, being the part of TRIPS regime, product patents can also be granted in India. This patent regime grants the patentee a larger hold on availability, accessibility, quantity and price value of the drugs. This has increased the power of patentee which may be abused by them in certain ways as discussed earlier in introduction. India is a hub of big pharmaceutical industries which breathe on patents. According to Organization of Pharmaceutical Producers of India, the rank of India is third in terms of volume of production in pharmaceutical industry.<sup>11</sup> Due to the demand of patented products and to check the monopoly or abuse of the patent rights, Indian Patent Act contains very comprehensive provisions of compulsory licensing. These provisions are supportive in providing the adequate supply of needed product and maintain public morality.

According to Indian Patents Act, 1970, compulsory license can be granted for the patents after expiry of three years of patent. Some of the sections of Indian patent act which deals with the compulsory license are:<sup>12</sup>

- Section 90 deals with the terms and conditions of compulsory license.

1. The royalty if any reserved to the patentee having regard to
    - The nature of the invention
    - The expenditure incurred in making/developing the invention, obtaining a patent and keeping it in force
  2. Licensee should work commercially on patent to the fullest extent with reasonable profit.
  3. Reasonable affordable price of patented article should be available to the public.
  4. Compulsory license is a non-exclusive license
  5. Right of licensee is non assignable
  6. Compulsory license predominantly supplies the product in Indian market and may also be exported if needed.
  7. Licensee can't import patented article but if the Central Govt. feels it necessary then it may be imported.
- Section 84 states that the controller of patents can grant compulsory license under any of following three conditions:
1. The reasonable requirements of the public with respect to the patented invention have not been satisfied; or
  2. The patented invention is not available to the public at a reasonable price; or
  3. The patented invention is not worked in India.
- Section 92 provides special provision of compulsory license. It states that the Controller of patent can file application of compulsory license under following conditions:
1. A circumstance of national emergency
  2. A circumstance of extreme urgency
  3. A case of public non-commercial use
- Section 92A deals with the compulsory license for export of patented pharmaceutical products. It states that CL can be granted solely to manufacture and export of the pharmaceutical product to the needy country. Controller General may add some terms and conditions as per the requirement. Patented pharmaceutical products include:
1. Drugs
  2. Ingredients necessary for their manufacture
  3. Diagnostic kits required for their use
- Section 94 deals with termination of compulsory license. It states that the Controller may terminate compulsory license if the circumstances that gave rise to the grant exist no longer and are unlikely to

recur. CL holder has the right to object to such termination. Also if the CL holder is not able to fulfil the requirements for which the compulsory license was granted, his license can be terminated.

- Section 100 provides patents for the government use. It states that the government can acquire the patented invention for its own use in return of some compensation to the patentee. The government is required to notify the patentee about the use and extent of use of the invention. The patentee however can challenge such a use or the terms of such use.
- Section 102 states that the government can acquire the patented invention for public purpose. Patent holder loses all the rights on the invention and gets some compensation in return. The patent holder cannot challenge the acquisition but can ask for more compensation.

### Issues related to Compulsory License

#### Creation of Gray Market

Local supply of patented product may lead to the creation of gray market in different ways. Gray markets arise when a product is designed and destined for a particular market, but it is also brought in another market known as a 'gray market' to sell it for less than its list price in the targeted market. In comparison to black marketing which involves counterfeit or illegal goods, gray marketing may not be called illegal.<sup>13</sup> But they definitely cause revenue loss and pose the economic burden on the country. Gray marketing has a big role in infringement of the intellectual property rights. In case of compulsory licensing, where the generic company (licensee) is given rights to manufacture and sell the patented drug to the target country only for which the compulsory license is granted but instead, the company itself or its dealers sell the drug to other countries also. This is mainly seen when the license is granted for the import of drugs from other country. Also when compulsory license is granted to some company for manufacture of a certain drug then some other generic companies also start making same drug without any license. Such drugs are usually counterfeited. This is a great economic loss to the country as well as patentee. Hence, gray marketing needs to be checked in case of compulsory licensed products as well. By adopting certain steps one can keep check on gray marketing to a major extent. If possible, the original price of the

drug can be kept low enough so that it could not divert customers towards the gray markets. Manufacturer or the distributors or sometimes both are responsible for creation of gray market. In such situation gray dealers should be tracked and appropriate actions should be taken against them. Gray dealers can also be converted to official sales partners. This would be beneficial for both gray dealers as well as manufacturer. In case of Pharma goods, every batch should have stamps of "only to be sold in particular country" or "only for export" so that the buyers should also be aware of gray product. Special watermarks and holograms should be used on products that would be difficult to copy. The consumers can be made aware that gray market drugs may not be of same potency and quality as the original ones. For example, in 2002, *Procrit*®, a drug used to treat anaemia in cancer and AIDS patients was counterfeited by using non-sterile tap water in it causing infection in already weak patients.<sup>14</sup> The doctors also should not prescribe the gray or counterfeited products and report if found someone selling it. Scarcity derives the behavior of gray market. Manufacturer can also reduce gray market by giving voluntary license which will meet the demand and put a check on the gray products. Tiny electromagnetic devices can also be placed in drug packaging to track the products as they move through distribution system. Most importantly every government should make certain laws which could strictly check the export /import of products. By undertaking some of these steps, gray marketing can be avoided but it should not put a hurdle in the way of compulsory licensing of the useful patented products. The presence of gray market is a sign of lack of supply of the product as per the demand in the particular area. So this may also give the alarm for the requirement of the product in that area and to increase its supply.

#### **Difference in standards of National Emergency**

National emergency has no international standardized definition. This is one of the issues being raised from time to time against compulsory licensing that no fixed standardized definition of national health emergency is available. Having a fixed, narrow and rigid definition of national emergency which is applicable to all the countries is a twisted task because every country has their own health problems, different diseases, lifestyle and population. A state of health emergency in a country with lesser population is different from that of a big nation. For example, 1% of population of a country suffering from a disease may

account as a state of national emergency in the country like India where 1% of population is equivalent to 12.5 million people, while in the country like Canada where 1% population is equivalent to 0.351 million people, it may or may not be accounted as state of national emergency.<sup>15, 16</sup> The outbreak of Swine Flu in India in 2014-15 caused death of 2,123 people. The number of infected individuals is reported to be 34,656 till 6<sup>th</sup> April, 2015 (according to the Health Ministry).<sup>17</sup> The number of patients accounts to a very less population of the country and the adequate availability of the drug to them, does not make this outbreak fall in the category of national state of emergency in the country. Similarly, environmental conditions, resources available in a country are also important parameters in deciding the state of emergency. All these parameters are different in different countries.

Various countries have laid down various parameters and criteria in deciding the state of emergency in their country. For example, The United Kingdom's Civil Contingency Act 2004 defines an emergency as "An event or situation threatens damage to human welfare only if it involves, causes or may cause loss of human life, human illness or injury, homelessness, damage to property, disruption of supply of money, food, water, energy or fuel, disruption of system of communication, disruption of facilities for transport, or disruption of services relating to health."<sup>18</sup> The National Disaster Medical System, a public health emergency is an emergency need for health care/medical services to respond to a disaster, major outbreak of an infectious disease, bioterrorist attack or other significant or catastrophic event.<sup>19</sup> Also WHO has given various definitions of disaster, natural hazards, emergency, epidemic, etc. which can be followed at the times when necessary.<sup>20</sup>

#### **Apprehensions of the Patent holder**

Applicant of compulsory license who has not spent a single penny on the invention cannot be equated with the inventor. Certain patent holders are of the view that compulsory license will dishearten the inventors and will discourage further innovative activities. According to them, the patentee spends a lot of money and efforts to develop the invention but the compulsory license holder gets the benefit without any effort. In explanation to this, compulsory license will only be granted if some violation is taking place or the demand of drug supply is not completed. Also, the applicant has to apply for the voluntary license to the patentee first and then can file for the compulsory

license only if got rejection from patentee. If all these conditions are not met only then compulsory license is issued. Even after the grant of compulsory license, people are given chances of revocation. It is found that companies under compulsory licensing obligations come under pressure to continue the innovativeness in order to remain ahead to their competitors.<sup>21</sup> This leads to enhancement of innovation in them rather than declining it. The patent holder also gets some royalty of his innovation for which compulsory license has been granted. So by the issuance of license, they earn royalty on their product without even manufacturing or marketing it. Hence bottom-line is that if there is no violation of law, the compulsory license will not be granted for the invention. Otherwise, in order to protect the public morality, the government has to take the action. So, patent holder should take care that all the rules and regulations are followed and should not provide any niche area for the compulsory licensing.

#### Royalty Free Practice or Low Royalty

Compulsory license is granted in the situation of crisis, emergency or urgency which means it is granted for the people in great need. At the time of crisis, the product is required in bulk as well as in affordable prices so that it should be in reach of every one belonging to any financial class. In that case royalty for compulsory license cannot be given very high so that price should not get higher. But still patentee is given some royalty as per the agreement. Royalty is decided on many bases like market value of product, area of marketing, quantity of product to be marketed, percentage of customers, time period of license etc. If marketing is to be done in bulk then royalty is mostly less because even 1% of huge quantity means a lot of money and it also shows that the requirement of the product is higher. Royalty can be higher in middle and high income countries with low burdens of disease and royalty is much lower for low income countries with higher rates of disease burden. On the other hand, it is expected that royalty free grant of compulsory license gives chance to local or small industries to develop and utilize patented invention. This enhances their manufacturing skills and efficiency which is helpful for their future development and that of nation and society as well. As in Xerox case in which royalty free grant of compulsory license opened up opportunities for other such companies to invent around. When the variety of same product is available in the market, its price is

definitely affordable due to competition which is beneficial for the society. Nonetheless, patent holder deserves certain royalty for their efforts and invention and so reasonable royalty terms should be negotiated at the time of agreement.<sup>21</sup>

#### Case Studies of Compulsory License in Pharmaceuticals in India

India granted its first (and sole) compulsory license in March 2012 to generic manufacturer Natco against the patentee Bayer's chemotherapy drug, *Nexavar*® (Sorafenib Tosylate). The drug is used in treatment of Renal Cell Carcinoma (RCC) and Hepato Cellular Carcinoma (HCC). The drug was priced at INR 2.8 lakh for a month therapy by Bayer which was claimed to be sold at INR 8800 for a month of therapy by Natco, thereby cutting the price to 97%. In return, Bayer got the royalty of 6% which was latter raised to 7% on the appeal of Bayer.<sup>22</sup> Now Natco is selling the drug under the name of *Sorafenat*®.<sup>23</sup> The saga began in December 2010 when Natco approached Bayer to grant voluntary license to manufacture *Nexavar*® but Bayer turned it down.<sup>24</sup> Then in 2011, Natco applied to the Controller for the grant of compulsory license under Section 84, stating:

- that the patented invention was not available to the public at the reasonably affordable price; or
- reasonable requirement of the public with regard to the patented invention was not being satisfied, or
- that the patented invention was not worked in the territory of India.

Recently, many discrepancies have been found in Form- 27 filled by Bayer. It is found that Bayer did not file Form- 27 in 2008 and 2010. In year 2009, it filled two separate Form- 27 and refused to clarify which one is accurate. Also it has been found that Bayer exported more drug units every year than it sold (up to 700% more). Even after three years of the compulsory license, Bayer has not amended the price of the drug. It is selling the drug at the same price. This could led to revocation of Bayer's patent under Section 85, as it is found that the public requirements of the drug are still not been satisfied. Section 85 says that if a single patient is away from the access of the drug, the public requirements cannot be said to be satisfied. According to Indian Patent Office, Natco has also not submitted any of its quarterly sales figures for the drug in the three years. So, government should keep a check on filling of Form- 27 and sale of patented drugs.<sup>23</sup>

The application for the grant of compulsory license for *Dasatinib* was filed by BDR pharmaceuticals in

March 2013. *Dasatinib* is sold by Bristol-Myers Squibb under the name of *Sprycel*®. It is used in the treatment of chronic myeloid leukaemia. In India, a month's therapy of this drug costs about INR 1 lakh. BDR Pharmaceutical claimed to sell the drug at INR 8,100 for a month therapy. But the application was rejected by the Patent Office on the grounds that the *prima facie* case has not made out by BDR Pharma under Section 84. The company did not make enough efforts to obtain a voluntary license for the drug from the patent holder.<sup>25,26,27,28</sup> Later in 2014, Health Ministry planned to compulsory license *Dasatinib* under Section 92. But, Department of Industrial Policy and Promotion (DIPP) turned it down stating that the use of Section 92 is impermissible as no national emergency or national urgency situation is prevailing in the country.<sup>10, 29</sup> Though, lot of efforts were made by BDR Pharma and Health ministry to get the compulsory license for *Dasatinib* but due to lack of solid base, the compulsory license could not be granted.

*Trastuzumab*, sold under the brand name of *Herceptin*® by Swiss company Roche Pharmaceuticals, is used in treatment of breast cancer. This drug was patented in India.<sup>30</sup> Around 25000 Indian women are diagnosed with breast cancer each year. It is found that only 5-6% of Indian patients get access to the drug.<sup>31</sup> The underlying problem was the high price of the drug. It costs around INR one lakh for a month therapy. In 2013, Indian Government took a step forward to solve this problem by starting the process for granting compulsory license of *Herceptin*®.<sup>32</sup> But later in 2013, Roche decided not to pursue the patent in India.<sup>33</sup> The company took this decision on the basis that there were no biosimilars of *Herceptin* in India at that time, so the patients had to buy its products. Also at the same time company can get saved from compulsory license.<sup>31,32</sup> But it certainly opened the market for the generic version of the drug. Many big Indian Pharma companies got busy in developing the biosimilars of *Herceptin*®. The threat of compulsory licensing could make this possible. In 2014, India based Biocon Ltd. along with U.S. Partner Mylan Inc. proposed to sell the drug *Herceptin* under the name *Canmab*™. They proposed to sell it in two different dosage sizes. A 440 mg vial has MRP of INR 57,500 while a 150 mg vial costs INR 19,500. But this price is only 25% less than the Roche's price of original drug.<sup>34</sup> Later in 2014, High Court ordered Biocon to prove that their product had

undergone sufficient testing as Roche claimed that the drug makers could not have carried out adequate clinical trials in such a short period of time. But Biocon denied the allegations.<sup>35</sup> It is a great hope to get the cheaper version of life saving *Herceptin* in Indian market soon. All this could become possible due to the threat and impact of compulsory licensing.

*Indacaterol* patented by Novartis in India and is sold under brand name *Onbrez*®. This drug is used to treat compulsory obstructive pulmonary disease. Cipla, an Indian generic pharmaceutical company, filed the petition to the DIPP in late 2014 and stated that COPD has reached the epidemic proportions in India. It also stated that *Onbrez*® imported in India by licensee Lupin only met the demand of 0.03% of population which is not sufficient. Also, the price of the drug is not reasonable. So Cipla asked to DIPP to issue compulsory license for *Onbrez*® under Section 92 and Section 66. Cipla launched its generic version of *Indacaterol* and offered to sell it at a price almost 42% lower than Novartis. But Health Ministry did not find strong basis of this application and suggested Cipla to file fresh application under Section 84.<sup>36</sup>

#### Alternatives to Compulsory License

Compulsory license is a provision, which is enforced by the government to license the drug patent to a third, interested party without the consent of the patentee under the conditions stipulated by patent legislations. The government should balance public good and rights of the patentee. Issuance of compulsory license frequently may dishearten the patent holder and may prove to be a deterrent to innovation. To counter this, several measures are suggested as below as alternatives to the compulsory license of drug patents:

- Government may increase expenditure in healthcare sector and extend the insurance umbrella to cover larger population to improve their access to expensive and life saving drugs.
- Increase in government funded research labs in poor countries will make them self-sufficient and enhance their capacity to manufacture more drugs. Governments of developed countries can also do so for development of developing countries.
- Pricing of patented drug can be negotiated and fixed according to the economy of the country. By doing so patentee can earn larger profits from rich and developed countries and

lesser profits from least developed and developing countries.

- Patent holders can be encouraged to voluntarily donate medicines as charity in least developed countries.
- The patent holder may be given tax benefits and other incentives for lowering the prices of patented drugs.
- Government may purchase the patent of expensive life saving drugs from the patentee, which may be licensed at a lower price to a local drug company for easy public accessibility.
- Creation of collective rights organizations by government.

Above alternatives may not obviate need for compulsory licensing but they may certainly be useful in reducing the severity of the effects of this provision.

### Conclusion

The main aim of compulsory license is to improve access of public to patented expensive medicines. This also increases the competition in market and cuts down the price of patented drugs, because dominance of a drug in market may lead to high price and hence abuse of patent may result. The competition among various companies for a drug is always in favour of public. Competition will increase the supply of the product and thus lowers its price. Government may take steps in lowering the cost by controlling the profit percentage to some maximum limit. By these steps, price of drug should be controlled at the initial steps and may not demand compulsory license in future. This may protect the right to health and access to medicines by public. Hence, the countries should include compulsory licensing as their essential public health policy tool. But if a country goes on a spree to grant compulsory licenses as a regular measure for abuse of IPRs and anti-competitive practices then it may shrink the foreign direct investment of a country as we can see this in Annual Report 301 of U.S. in which they have threatened not to trade with the countries who are issuing compulsory licenses on their patents. Therefore, the compulsory licensing must be resorted only in extreme cases when there is no other way out.

Moreover TRIPS and Doha Declaration considered compulsory license as an important provision so as to provide health benefits to the people without any

discrimination on the basis of color, caste, creed or even country. These laws provide flexibilities because the requirement of every country and every disease is different. These laws along with the flexibilities should not be under any sort of political pressure and should be used in favour of public interest along with benefits to the patent holder.

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